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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,914	11/15/2005	Kaoruko Urai	URAI5	1605
1444 7590 10/04/2010 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER SIMMONS, CHRIS E	
			ART UNIT	PAPER NUMBER
			1612	
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			10/04/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/556,914

Applicant(s)

URAI ET AL.

Examiner

CHRIS E. SIMMONS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 6, 8-13, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 6 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/04/2010 has been entered.

Applicants' arguments, filed 08/04/2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1, 5, 6 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0119105 (cited in 07/22/2009 Office action) in view of US 4,748,198.

The '105 patent teaches tooth coating compositions containing shellac, a solvent of the shellac, and mica titanium as the main constituents.

The particularly preferred content of shellac is from 5% by weight to 15% by weight. When the shellac resin is less than 1%, the composition is too brittle for tooth coating and when it is above 20%, it is too viscous to thinly coat the tooth and has inferior drying properties [0012]. One embodiment teaches a composition comprising 12% shellac (Example 4) (note the whole composition contains from 6% to 12% shellac [0055]). In addition to shellac as the coat-forming component, one kind or a combination of

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two or more kinds of other resins (e.g., rosin; [0014]) can be added to the composition at a suitable amount. Such material provides improved luster of the coat and more improved dispersion of mica titanium or pigments [0013].

Mica titanium is a substance obtained by coating a mica powder with a thin film of titanium oxide (a pigment) [0017]. A particularly preferred compounding amount of mica titanium is from 2% by weight to 15% by weight of the whole composition [0018]. The '105 patent does not expressly teach the claimed concentration of rosin, nor comment on the drying time or duration of luster.

The '198 patent discloses coating materials for the surface of teeth comprising 100 weight parts of a polystyrene resin or high-impact polystyrene resin and 1 to 60, preferably 5 to 40 (col. 4, ll. 21-25), weight parts, of rosin. See abstract. When rosin or a rosin derivative has been added to the resinous composition, the adhesion of the resulting protecting film to the surface of a tooth is improved (col. 3, ll. 3-6). When the composition is dissolved in an organic solvent and coated on the surface of a tooth, the rosin added thereto has the property of showing strong adhesion to the tooth substance and adhering thereto, and forming a hard film thereon, after the organic solvent has been volatilized off. Since the rosin or its derivative tends to lower the rate of volatilization of the organic solvent, it is added and used in a proportion of 1 to 60, preferably 5 to 40 weight parts, per 100 weight parts of the polystyrene or high-impact polystyrene resin. That is, when the rosin or its derivative is used in an amount of less than 1 weight part, it provides a protecting film which is so poor in the adhesion to the surface of a tooth that it may be released therefrom during cavity preparation under water pouring or water washing-air gun drying. On the other hand, use of the rosin or its derivative in an amount of higher than 60 weight parts is practically unsuitable, since the resulting film does not only show reduced or limited durability with respect to an alcohol contained in a dental bonding material, but does also require a longer drying period of time (col. 4 ll.15-36). It is noted that the '198 patent discloses the range of rosin of 0.5% to 29% (i.e., where 5 to 40 weight parts is added to 100 parts of the polystyrene or high-impact polystyrene resin).

Thus, the '105 patent teaches that inclusion of rosin in a resin-containing tooth coating composition improves adhesion of the composition to the tooth and the durability of the material (i.e. durability of luster), and that the concentration of rosin (%wt) directly effects the adhesivity -- and consequently the durability of luster -- of the tooth coating composition and the drying time of the composition (i.e. the concentration of rosin is a result effective variable).

The reference does not expressly teach shellac or the specific concentration range of rosin claimed. See paragraph bridging columns 4 and 5.

It would have been obvious to one of ordinary skill in the art to modify the composition of the '105 patent to specifically select rosin as the additional resin (See the '105 patent [0013] and [0014]) to be included in combination with the shellac, as rosin was taught to improve adhesivity of the composition to tooth surfaces and possibly improving luster (See the '198 patent).

With regards to the amount of rosin to be included, it would have been obvious to one of ordinary skill in the art to adjust the "suitable amount" of rosin included in the composition of the '105 patent to the amounts instantly claimed because the concentration of rosin was recognized as a result effective variable, specifically effecting the adhesion of the resulting protecting film to the surface of a tooth, the luster, and the drying time of the composition. It has been held that when a particular parameter has been recognized as a result-effective variable, i.e., a variable which achieves a recognized result, determination of optimum or workable ranges would be characterized as routine experimentation. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) and *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Thus the amount of rosin included in the composition of the '105 patent would have been routinely optimized by one having ordinary skill in the art, thereby rendering obvious the levels recited by the instant claims. The holding of obviousness is

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based on legal precedence that optimization of a result effective variable through routine experimentation is *prima facie* obvious. (*In re Aller*, cited above).

Regarding new claim 21, the dental coating suggested by the prior art is fully capable for the claimed intended use of the composition in instant claim 21.

Response to arguments

Applicant argues that unexpected properties have been demonstrated by examples in the disclosure as summarized by Table 3 (attached to last page of response) and Table 4 (attached to last page of current response). These tables summarize the data of Examples 1-8, comparative examples 1-6 and results of test 1-4. Applicant submits that the range of the content for rosins Examples 1-8 with the exception of Example 5, is 5% to 15% and a range of total content of shellac and rosin for Examples 1-8, with the exception of Example 5, is 15% to 25%. Applicant notes while Example 5 has excellent properties of luster, durability, removal easiness and hiding power, its drying time of 180 is too long. Applicant further notes in cases where rosin content is above 15%, and in which the total content of shellac and rosin exceeds 25%, as in Example 5, the tooth coating did not get sufficient results in tests 1-4. Applicant argues that the data demonstrates criticality of the specified amounts of shellac and rosin in the composition as claimed to obtain unexpected results including drying time of less than 60 seconds and a durable duration of luster of at least 4 hours.

The examiner does not find that unexpected results in the data presented. Examiner submits that it is already known as described in the '198 patent that rosin tends to lower the rate of volatilization of the organic solvent and thereby increasing drying time as well as showing reduced or limited durability. As such it is expected that higher amounts of rosin would increase drying time as demonstrated by the data submitted in the instant case. Additionally, it is already known that when the amount of rosin is too low it provides a protecting film which is so poor in the adhesion to the surface of a tooth that it may be easily

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released therefrom (see '198 patent, col. 4 ll.15-36), which would reasonably lead to poor durability of luster and other properties rosin provides to tooth coating compositions such as dispersibility of pigments which would lead to poor hiding qualities (see '105 patent).

Even if, applicant had demonstrated unexpected results, *in arguendo*, the examiner submits that the claimed ranges are not commensurate in scope with the data presented in Examples 1-8.

Accordingly, examiner does not find unexpected data that show the criticality of the claimed percent ranges for rosin or the total percent ranges for shellac and rosin.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Primary Examiner, Art Unit 1651

/C. E. S./
Examiner, Art Unit 1612